

## REMARKS

### A. Status of the Claims

Claims 13 and 15-36 were pending at the time of the Action. Claims 15 and 16 are amended herein. Support for the amendments can be found, at least, in the claims as filed. No new matter is added.

### B. Rejections Under 35 U.S.C. § 103

#### 1. **Claims 13, 15-27 and 33-36 are Non-obvious Over Cohen *et al.* in View of English *et al.***

The Action rejects claims 13, 15-27 and 33-36 as obvious under 35 U.S.C. § 103(a) over Cohen *et al.* (August 2000, *International Rice Research Notes*, 25:4-10). In particular, it is asserted that Cohen *et al.* teach seed blends comprising a first transgenic crop seed with an insecticidal transgene and a refuge seed that does not comprise an insecticidal transgene and that 4-20% of a crop must be the refuge plant. It is thus stated that it would thus be obvious to modify the seed blends of Cohen *et al.* to arrive at the claimed invention. Applicants respectfully traverse for the following reasons:

The Action also states on page 2, paragraph 5, that claims 17 and 18, and all dependent claims, are not interpreted as limiting the seed to have a seed treatment, as parent claims 15 and 16 only list possible treatment. Applicants note that claims 15 and 16 are amended herein to recite that the transgenic crop seed and refuge seed are treated with a seed treatment, and thus this aspect of the rejection is moot.

#### a. **The Claimed Invention Yields Unexpected Results**

Provided herewith is Exhibit A, the Declaration of Dr. Graham Head under 37 C.F.R. § 1.132, demonstrating that the claimed seed blends yield surprising and unexpected results. In

particular, as explained in the Declaration, the claimed seed blends surprisingly resulted in reduced insect damage on non-Bt refuge plants (plants with no insecticidal transgenes) planted in fields with seed blends, relative to fields with 100% non-Bt plants (refuge). For instance, refuge plants that were planted as part of a 90%/10% transgenic Bt/ non-Bt refuge blend resulted in a decrease in the percentage of plants attacked by insects from 65% to 56% and a decrease in the percentage of plants attacked by insects from 65% to 47% for refuge plants planted as part of a 95%/5% transgenic Bt/ non-Bt refuge blend. The results demonstrate a greater than **27% overall decrease** in the total number of refuge plants attacked by insects.

Furthermore, the refuge plants within the seed blends that showed damage due to insect feeding demonstrated less damage from the insects. In particular, plants that were attacked in the 100% refuge field showed on average 1.8 inches of stalk tunneling, while refuge plants within the 90%/10% blend showed only 1.3 inches of stalk tunneling and plants within the 95%/5% blend showed only 0.8 inches of stalk tunneling on average.

Such results demonstrate that refuge plants planted as part of the claimed seed blends are attacked less and sustain less damage than those planted in pure refuge fields. The decrease in insect damage greatly contrasts the teaching in the art at the time of filing, particularly Lambert *et al.* (*Proc. Beltwide Cotton Conf.*, 1996, vol. 2, pages 931-935), which discloses that seed blends cause greater damage. For instance, Lambert *et al.* teach that seed blends are not practical, indicating that “treatments incorporating blends of *B.t.* and non-*B.t.* seed (85:15 and 75:25) sustained too much fruit damage and yield loss for the blended seed concept to be practical” (Lambert *et al.*, p. 933, 2<sup>nd</sup> col. 1<sup>st</sup> paragraph).

In particular, Lambert *et al.* found that:

Numbers of larvae and fruit **damage increased** as the percentage of *B.t.* seed in the blends decreased. Conversely, seed cotton **yields decreased** as the percentage of *B.t.* seed in the blends decreased.

Lambert *et al.*, p. 932, 2<sup>nd</sup> col. 4<sup>th</sup> paragraph, (emphasis added).

The reference further refers to other studies with the same findings:

The results of this field study were similar in many respects to those obtained in filed studies conducted earlier in North Carolina (Mahaffey *et al.*, 1994, 1995) where various *B.t.* seed blends (75-100% *B.t.* seed) were damaged by bollworm to the extent that **significant yield reductions (ca. 10-20%) resulted**.

Lambert *et al.*, p. 932, 2<sup>nd</sup> col., 6<sup>th</sup> paragraph, (emphasis added).

The results demonstrated in Dr. Graham Head's Declaration are therefore surprising and would in no way be expected in view of the art at the time of filing.

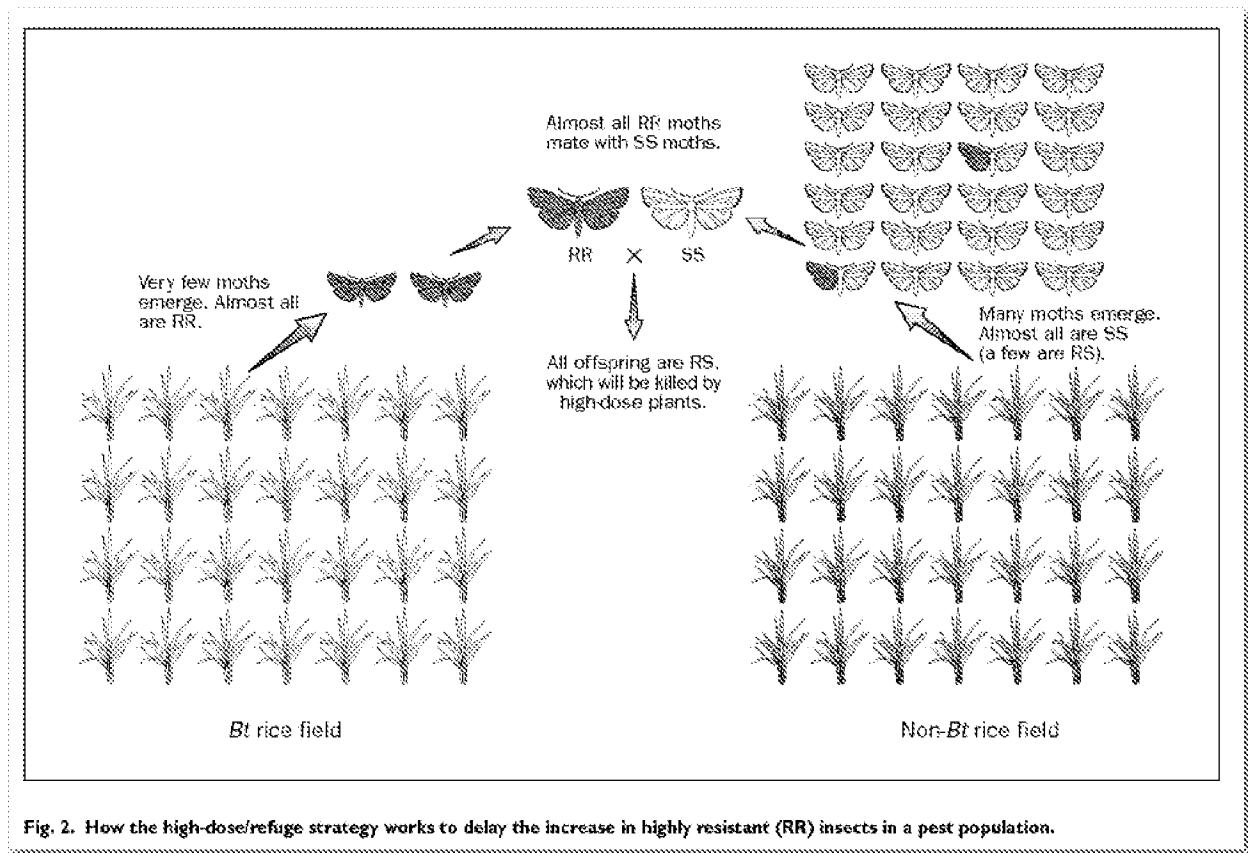
**b. Cohen *et al.* and Lambert *et al.* Teach Away From the Claimed Invention**

**i. Cohen *et al.* Teach That Seed Blends Comprising an Insecticidal Transgene Targeting Lepidopteran Insects Would be Unsuitable**

The claimed invention is directed to seed blends comprising a mixture of transgenic (insecticidal) and refuge (non-insecticidal) seeds, wherein at least one of the transgenes in the transgenic seed targets a lepidopteran insect. It is well known that lepidopteran insects are highly mobile, easily moving from one plant to the next. While Cohen *et al.* is asserted to disclose seed blends comprising a transgenic seed and a refuge seed, the reference actually teaches away from such blends for use against **mobile target pests**.

Cohen *et al.* teach that, in order to avoid insect resistance, a "high-dose" resistance management strategy must be employed. Such a strategy relies upon maintenance of susceptible insects on refuge plants to mate with the resistant insects emerging from the transgenic plants

and deployment of transgenic seeds with a titer of the *Bt* toxin high enough to kill almost all resulting progeny. See Figure 2 of Cohen *et al.*, reproduced below.



Cohen *et al.* continue to teach that a high-dose strategy would not work for mobile pests, such as Yellow Stem Borers (YSB) and Striped Stem Borers (SSB), both of which are insects from the order Lepidoptera, stating that “within-field” refuge mixtures, such as those claimed, as opposed to refuge fields planted separate from transgenic fields, would result in “some of the insects [feeding] on *Bt* and non-*Bt* plants, *thereby ‘diluting’ the high-dose titer in Bt plants.*” (Cohen *et al.*, p. 5, 2<sup>nd</sup> col., 3<sup>rd</sup> full paragraph, emphasis added). As Cohen *et al.* generally teaches that anything but high-dose titers in transgenic plants will not effectively reduce insect resistance, the reference clearly teaches away from such blends for use against mobile target

pests. One of skill in the art, based on the teaching in Cohen *et al.*, would have no reason to employ a resistance strategy that is anything less than a high-dose strategy, such as a within-field seed blend, which is taught to ‘dilute’ the high-dose titer for mobile pests. In fact, those of skill in the art would be directed away from using the claimed seed blends to target lepidopteran pests.

Although the Action states on page 4 that the disclosure in Cohen *et al.* does not teach that “blends should not be made,” Cohen *et al.* do disclose, as described above, that within-field blends for use with mobile pests that move from plant to plant during development, such as lepidopteran pests, would lead to increased pest resistance and thus would not be suitable for control of such insects. The disclosure in Cohen *et al.* criticizes, discredits and discourages the use of seed blends in such a way that one of skill in the art would be led in a path divergent from that taken by the Applicants, teaching that such blends are unsuitable for resistance management. Such disclosure constitutes teaching away, by its very definition as described below. In contrast, the Declaration of Dr. Graham Head shows that the transgenic insecticidal plants in a seed blend actually suffer no more damage than the same plants incur in a pure stand when the insecticidal plants contain multiple insecticidal transgenes targeted at Lepidoptera. That is, there is no reduction in toxin titer in these cases, in direct contradiction to the claims of Cohen *et al.* Therefore, a seed blend approach is appropriate for resistance management in the cases described by the Applicants.

To support the asserted lack of teaching away MPEP 2123 II is cited, including reference to three cases, *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994), *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004), and *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

The *Gurley* court, however, found that a reference teaches away when a person of ordinary skill, upon reading the reference, would be “discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” (citing *In re Caldwell*, 50 C.C.P.A. 1464, 319 F.2d 254, 256, 138 U.S.P.Q. (BNA) 243, 245 (CCPA 1963), (a “reference teaches away if it leaves the impression that the product would not have the property sought by the applicant.”) *Id* at 27 F.3d 554, 31 USPQ2d 1132. One of skill in the art reading the Cohen *et al.* reference would clearly choose against seed blends to target mobile pests, and instead use separate refuge fields, thereby being “***led in a direction divergent from the path that was taken by the applicant.***” (emphasis added). Consistent with this, Cohen *et al.* teaches seed blends will increase the development of resistance in lepidopterans (mobile insects) and render the refuge blends unable to perform the intended task of decreasing insect resistance, thereby “not having the property sought by the applicant.” The court in *In re Gurley* found that these facts render the disclosure in the cited reference as teaching away.

The references in question in *In re Gurley* were held as failing to teach that the claimed substrate was unsuitable for the intended purpose. The court found that the mere indication that the composition was “somewhat inferior to some other product for the same use” does not rise to the level of showing non-obviousness. In the present case, however, Cohen *et al.* does not merely indicate that seed blends for lepidopteran insects would be “somewhat inferior” to separate refuge fields, but rather that that such blends would dilute the titer of insecticidal agent in the seed, thereby increasing the prevalence of insect resistance. Cohen *et al.* therefore teaches that the currently claimed invention would not work for its intended function which is exactly what the court in *In re Gurley* found constitutes teaching away.

Similarly, the court in *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004) held that the “mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does ***not criticize, discredit, or otherwise discourage the solution claimed.***” *Id.* In the present case, however, the cited art does “criticize, discredit, or otherwise discourage the solution claimed.” *Cohen et al.* directly teach that using within-field seed blends for mobile pests would “dilute” the dose *Bt* toxin, which would in turn result in increased insect resistance. As the entire purpose of the blend rather than 100% transgenic insecticidal seed is to manage resistance, there could not be any more explicit teaching away.

Regarding *In re Susi*, the court held that, although the cited reference disclosed compounds that were “most particularly preferred” over those closer to the claimed invention, such “particularly preferred” embodiments did not constitute teaching away because the only difference present between the claimed invention and the prior art “seems to be of ***little importance.***” (*Id.*, emphasis added).

This is distinct from the present case, where the difference between using separate refuge fields or in-field blends is not of “little importance” or a choice of one embodiment over a “particularly preferred embodiment.” In fact, as described above, the reference teaches that in-field seed blends will increase the development of resistance in mobile insects, such as the claimed lepidopterans, thereby rendering such seed blends ***unable to perform the task intended,*** namely prevent insect resistance. In fact, once resistance develops the entire field becomes susceptible to insect attack.

Analysis of the facts of the very cases cited in the Action related to those of the current case in fact demonstrate that Cohen *et al.* constitute a teaching away and thus firmly demonstrate non-obviousness.

**ii. Lambert *et al.* Teach That Seed Blends Result in Unacceptable Fruit Damage and Yield Loss**

In addition to the teaching away found in Cohen *et al.* described above, Lambert *et al.* teach that seed blends are not suitable for agricultural use. As detailed above, Lambert *et al.* state that seed blends increase damage and decrease yields and thus are not practical (*see* Lambert *et al.*, p. 932, 2<sup>nd</sup> col. 4<sup>th</sup> and 6<sup>th</sup> paragraphs, and p. 933, 2<sup>nd</sup> col. 1<sup>st</sup> paragraph).

Additionally, Lambert *et al.* and references cited therein, specifically teach away from the use of seed blends targeting mobile lepidopteran insects. For instance, on page 933, second column, first paragraph Lambert *et al.* state:

Mallet and Porter (1992) suggested that seed mixtures may ***enhance resistance development*** in mobile insects. Thus it is likely that refugia will have to be accomplished through some means other than the blended seed strategy for bollworm.

Therefore, Lambert *et al.* and the references cited therein therefore clearly teach away from the claimed invention, as one of skill in the art would be discouraged from further pursuing seed blends as a method of pest control.

The Action, however, states on page 4 that Lambert *et al.* does not teach that seed blends should not be made, and thus does not teach away from the claimed invention. Applicants, however, fail to see how any more directed of a teaching away could be made. Lambert *et al.* clearly does not merely disclose multiple alternatives, identifying one or more as “preferred,” as was the case in *In re Susi* and *In re Fulton*, cited in the Action to support the asserted lack of teaching away. Instead, Lambert *et al.* describes experiments and findings of others that seed



blends targeting mobile pests were *impractical and thus unsuitable for pest management* due to the unacceptable fruit damage and yield loss resulting from such blends.

Additionally, research performed by others and referenced in Lambert *et al.* indicate that seed blends may *enhance resistance development in mobile insects*, such as lepidopteran insects, thereby leading one of skill in the art away from such blends. Such disclosure is exactly what the court in *In re Gurley* found comprises teaching away, stating that “a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Id* at 27 F.3d 554, 31 USPQ2d 1132.

One of skill in the art would have been dissuaded from pursuing seed blends in view of the negative results demonstrated by Lambert *et al.* As damage to the fruit or yield of a crop plant directly affects the profitability of such a crop, there would be no reason for one of skill in the art to attempt an insect resistance management strategy that is known to cause significant fruit damage or yield loss. This is especially true considering the insecticides used are employed to reduce crop damage and increase yield. Lambert *et al.* and the references cited therein therefore clearly fall under the court’s definition of teaching away.

**c. There Would be No Motivation to Arrive at the Claimed Invention in View of Cohen *et al.* and Lambert *et al.***

In addition to the unexpected results and teaching away in the art described above, one of skill in the art would have had no motivation to employ a transgenic seed blend to target lepidopteran insects, thus arriving at the claimed invention in view of Cohen *et al.* and further in view of Lambert *et al.* and the additional references cited therein. In particular, the claimed invention relates to a seed blend comprising at least one variety of transgenic crop seeds with two

insecticidal transgenes and refuge seeds in a mixture of about 80% to 99% transgenic crop seed, wherein at least one of the insecticidal transgenes is insecticidal to a lepidopteran insect.

As described above, however, Cohen *et al.* discloses that such seed blends do not effectively reduce insect resistance of mobile pests, such as those from the order Lepidoptera, as they lead to “dilution” of the toxin in the plant. See Cohen *et al.*, p 5, 2<sup>nd</sup> col., 3<sup>rd</sup> full paragraph and Figure 2, reproduced above. One of skill in the art reading Cohen *et al.* would therefore have no desire or motivation to employ such a strategy because it would lead to increased resistance to the transgene.

Such resistance would not only lead to further pest damage from resulting resistant pests in the immediate fields, but to resistance and damage problems in surrounding areas with potential global consequences. Lepidopteran insects are not only mobile during a single stage of development as caterpillars, moving from one plant to the next, but additionally in later stages of development as flying insects, such as moths. Moths and other flying insects can travel great distances carrying and spreading any resulting resistance alleles with them. One of skill in the art would be very sensitive to such an issue, which, in fact led to the development of resistance management strategies, and would therefore have no motivation to pursue a possible resistance management strategy likely to fail.

Furthermore, those of skill in the art understand that resistance management must be balanced with acceptable crop yield. Lambert *et al.*, however, discloses that seed blends with ratios 85:15 and 75:25 (transgenic:non-transgenic) “sustained too much fruit damage and yield loss for the blended seed concept to be practical.” (Lambert *et al.*, p. 933, 2<sup>nd</sup> col., 1<sup>st</sup> paragraph). Although resistant management strategies aim to delay the development of resistant insects, such strategies are of no value if they result in unacceptable damage or yield levels. The point of using transgenic seed at all is to reduce the amount of damage and increase the resulting yield, therefore one of skill in the

art would have no motivation to implement a resistance strategy resulting in significant crop damage and yield loss.

The combination of the known problems with seed blends to control pest resistance as described in Cohen *et al.*, and the damage observed by Lambert *et al.*, would leave one of skill in the art with no motivation to use transgenic seed blends to target lepidopteran insects.

**d. Cohen *et al.* Do Not Teach or Suggest All the Claim Elements**

Present claim 13 currently reads:

13. A seed blend comprising refuge seeds and at least one variety of transgenic crop seeds for use in planting in a field, wherein said seed blend comprises a refuge seed and a first transgenic crop seed in a uniform mixture; *wherein said mixture consists of from about 80% to about 99% first transgenic crop seed*, wherein the first transgenic crop seed comprises a first insecticidal transgene and a second insecticidal transgene, and wherein said refuge seed does not contain the first and second insecticidal transgenes, and further wherein at least one of the insecticidal transgenes is insecticidal to a lepidopteran insect.  
(emphasis added)

The Action states that Cohen *et al.* disclose that farmers must plant 4-20% of their crops as refuge plant, in an apparent attempt to assert that Cohen *et al.* teach or suggest the present embodiment of claim 13 requiring that the seed blends consist of about 80% to about 99% of the first transgenic crop seed. However, upon reviewing the cited reference it is apparent that Cohen *et al.* do not actually disclose that **4-20% of seeds in a mixed blend**, or even 4-20% of an in-field mixture, must be refuge, but instead, that “[f]armers growing *Bt* crops in the USA must plant 4-20% of the **crop land** to non-*Bt* cultivars, and these refuge **fields** must be within approximately 0.8 km of their *Bt* fields.” (Emphasis added). There is, however, no disclosure or suggestion regarding how much refuge in a seed blend would equate to the disclosed percent of **crop land**. The cited references therefore do not teach or suggest every element of the claims and the Action

provides no additional teaching in the art disclosing the claim element reciting that the claimed seed blends consist of about 80% to about 99% transgenic crop seed.

In sum, the unexpected results described in the Declaration of Dr. Graham Head, the teaching away from the claimed invention found in Cohen *et al.*, Lambert *et al.* and the references cited therein, the lack of any expectation of success in view of these references, the unexpected results demonstrated in the specification and the failure of the cited reference to teach or suggest every element of the claimed invention more than establish the non-obviousness of the claimed invention. The rejection is therefore believed to be moot and withdrawal thereof is respectfully requested.

**2. Claims 29-31 are Non-obvious Over Cohen *et al.* in View of English *et al.***

The Action rejects claims 29-31 as obvious under 35 U.S.C. § 103(a) over Cohen *et al.* (August 2000, *International Rice Research Notes*, 25:4-10) in view of English *et al.* (2000, U.S. Patent No. 6,023,013). In particular, Cohen *et al.* is applied as above to teach seed blends comprising a first transgenic crop seed with an insecticidal transgene and a refuge seed that does not comprise an insecticidal transgene and that 4-20% of a crop must be the refuge plant. English *et al.* is asserted to teach modified Cry3Bb genes, conferring resistance to the coleopterans southern and western corn rootworm. It is thus asserted that it would be obvious to modify the seed blends of Cohen *et al.* to have one of the two insecticidal transgenes be Cry3Bb as taught by English *et al.* and the second to be Cry1Ab, conferring resistance to the lepidopteran European corn borer, taught by Cohen *et al.*, to arrive at the claimed invention. Applicants traverse for at least the reasons below.

First, it is noted that claims 29-31 depend directly or indirectly upon claim 13, the non-obviousness of which has been fully established above. The addition of English *et al.*, cited to

disclose Cry3Bb to the rejection does not cure the defects discussed above and thus claims 29-31 are also clearly non-obvious.

The Action fails to identify any teaching or suggestion of a seed blend with a transgenic seed comprising two transgenes *insecticidal to different target pests*. In contrast, claims 29-31 require that the first and second insecticidal transgenes in the first transgenic crop seed of the seed blend of claim 13 are insecticidal to different target pests, that the different target pests are a coleopteran insect and a lepidopteran insect, and that the first or second insecticidal transgene encode a Cry3Bb, respectively. The Action states that this subject matter is obvious over the combination of Cohen *et al.* and English *et al.*, asserting that Cohen *et al.* discloses transgenic seeds to be used in a seed blend comprising two transgenes, referring to page 8, right column, paragraph 2 to page 9, left column, paragraph 1 of Cohen *et al.* for such disclosure. This portion of Cohen *et al.*, however, actually relates to the inclusion of two *Bt* genes directed to *the same insect* in a transgenic plant. In particular, Cohen *et al.* state the following:

If insects that are able to survive on a plant with one high-dose toxin are rare, then insects that are able to survive on plants with two high-dose toxins will be very rare indeed. If *such insects must be homozygous for resistance alleles for two different genes*, and if the frequency of the allele for resistance for each gene is  $10^{-3}$ , then insects of the genotype  $R_1R_1R_2R_2$  will occur at a frequency of only  $10^{-12}$ , i.e., 1 out of 1 trillion.

Cohen *et al.*, page 8, second column, first full paragraph, emphasis added.

Cohen *et al.* refer to insects homozygous for two genes thereby having a genotype of  $R_1R_1R_2R_2$ . In view of this, it would be clear to one of skill in the art that the *Bt* toxins the reference is discussing must target the same insect. It would be clear to one of skill in the art that such a resistance management strategy and the described logic behind the strategy differs significantly from the claimed seed blends comprising a transgenic plant with two transgenes targeting *different insects*. Cohen *et al.* simply do not teach or suggest seed blends with

transgenic seed comprising two insecticidal transgenes targeting different classes of insects as asserted in the Action. While English *et al.* is cited to disclose modified Cry3Bb genes, the reference does not disclose or suggest a seed blend that comprises two transgenes directed to two different target pests, and therefore does not cure the defect of Cohen *et al.*

In sum, the failure of Cohen *et al.* and English *et al.* to teach or suggest all the claimed elements, in addition to the deficiencies discussed above with respect to the rejection of claim 13, more than establish the non-obviousness of claims 29-31. The rejection is therefore believed to be moot and withdrawal thereof is respectfully requested.

**3. Claims 27, 28 and 32 are Non-obvious Over Cohen *et al.* in View of English *et al.* and Further in View of Narva *et al.***

The Action rejects claims 27, 28 and 32 as obvious over Cohen *et al.*, English *et al.*, as cited above, further in view of Narva *et al.* (2000, U.S. Patent No. 6,083,499). In particular, Cohen *et al.* and English *et al.* are applied as above, to teach the claimed seed blends where 4-20% of a crop must be the refuge plant and modified Cry3Bb genes conferring resistance to southern and western corn rootworm. It is also asserted that Narva *et al.* disclose PS149B1 toxins conferring resistance to western corn rootworm. The action states that it would be obvious to one of skill in the art to modify the seed blends of Cohen *et al.* in view of English *et al.* to have one of the two insecticidal transgenes be PS149B1 as taught by Narva *et al.* to arrive at the claimed invention.

Applicants traverse and note that, as claims 27, 28 and 32 depend directly or indirectly from claim 13, the arguments provided above regarding the rejection of claim 13 apply equally here. The addition of English *et al.* and Narva *et al.*, cited to disclose particular toxins, does not overcome the deficiencies of the rejection discussed in detail above. Claims 27, 28 and 32 are therefore non-obviousness and withdrawal of the rejection is thus respectfully requested.

#### **4. The Claims are Non-obvious Over Maqbool *et al.* in View of Cohen *et al.***

The Action rejects claims 13, 15-27, 29-30 and 33-36 as obvious under 35 U.S.C. § 103(a) over Maqbool *et al.* (1999, *Molecular Breeding*, 5:471-480) in view of Cohen *et al.* (August 2000, *International Rice Research Notes*, 25:4-10). In particular, it is asserted that Maqbool *et al.* teach rice plants comprising three insecticidal transgenes, Cry1Ac, Cry2A and snowdrop lectin GNA, conferring resistance to lepidopterans and coleopterans. Cohen *et al.* is cited to teach seed blends comprising a first transgenic crop seed with an insecticidal transgene and a refuge seed that does not comprise an insecticidal transgene and that 4-20% of a crop must be the refuge plant, as discussed above. The Action thus states that it would be obvious to one of skill in the art to modify the seed of the plants taught by Maqbool *et al.* to provide it in blends with refuge plant seed that does not contain the insecticidal transgenes, as described in Cohen *et al.*, to arrive at the claimed invention.

Applicants respectfully traverse. In particular, as Cohen *et al.* is cited for the reasons discussed above in the rejection of claims 13, 15-27 and 33-36, the deficiencies in the rejection over Cohen *et al.* discussed in detail above apply equally to the present rejection. Maqbool *et al.* is cited to generally disclose transgenic plants comprising the insecticidal transgenes, Cry1Ac, Cry2A and snowdrop lectin GNA. However, the reference does not disclose refuge seeds or seed blends and therefore cannot cure the defects of Cohen *et al.* described above.

In sum, the unexpected results demonstrated in Dr. Graham Head's Declaration, the teaching away from the claimed invention found in Cohen *et al.*, Lambert *et al.* and the references cited therein, the lack of any expectation of success in view of these references, the unexpected results demonstrated in the specification and the failure of the cited references to teach or suggest every element of the claimed invention more than establish the non-obviousness

of the claimed invention. The rejection is therefore believed to be moot and withdrawal thereof is respectfully requested.

**C. Double Patenting Rejection**

The Action rejects claims 13 and 15-36 on the ground of non-statutory obviousness-type double patenting, as being unpatentable over claims 19-40 of U.S. Patent No. 6,551,962. Applicants respectfully traverse, but note that a terminal disclaimer will be filed upon indication of otherwise allowable claims.

**D. Conclusion**

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned at (214) 259-0931 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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